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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,914	09/25/2003	Brian B. Lentrichia	11.025011	9190

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EXAMINER	
HINES, JANA A	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,914	LENTRICHIA, BRIAN B.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-50* is/are pending in the application.

4a) Of the above claim(s) *29,30,34-39,47 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-28,31-33,40-46,48 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 1, 2006 has been entered.

Amendment Entry

2. The amendment filed December 1, 2006 has been entered. Claims 1-25 have been cancelled. Claims 26-50 have been newly added. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 29, 30, 34-39, 47 and 50 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 26-28, 31-33, 40-46 and 48-49 are under consideration in this office action.

Withdrawal of Objections and Rejections

3. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 1-3, 6-7, 17, 19-20 and 22-23 under 35 U.S.C. 102(b) as being anticipated by Bruchez et al., (US Patent 6,274,323); and

b) The rejection of claim 18 under 35 U.S.C. 103(a) as being unpatentable over Bruchez et al., in view of Hurley et al., (US Patent 5,256,571) is

Response to Arguments

4. Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Objection

5. Claims 32 and 33 are objected to because of the following informalities: Claims 32 and 33 are duplicates of each other. Appropriate correction is required.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 26-28, 32-33, 40-42, 45-46 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Lentrichia et al., (US Patent 4,960,692).

The claims are drawn to a method for assaying a sample for the presence of a target molecule comprising: providing said sample suspended in a liquid wherein said sample is suspected of comprising said target molecule; immersing a filter into said liquid containing said sample and pulling said liquid containing said sample transversely through said filter using a pressure-controlling apparatus connected to said filter, wherein said filter comprises a sensor molecule attached thereto and said sensor molecule is capable of specifically binding to said target molecule, if present; binding of said target molecule to said sensor molecule; removing said filter from said sample; detecting the presence of said target molecule specifically bound to said sensor molecule. The dependant claims are drawn to the sensor molecule, the target molecule, control samples, secondary sensors, and secondary fluorophore labels.

Lentrichia et al., teach an assay employing binding pair members on particles and on a filter. Lentrichia et al., teach a method for determining (qualitatively or quantitatively) an analyte binding pair member in a biological sample comprising the steps of contacting particles having a first reagent binding pair complementary to the analyte with the biological sample under conditions to allow binding and allowing the reaction mixture passed through a filter where a member of a reagent binding pair is immobilized on the filter to trap either particles which have bound analyte binding pair member or particles which have not, leaving the other class of particles to pass through the filter for detection by resistive pulse techniques, light absorbance or scattering, enzymatic means or the like (col. 2, lines 15-28). Thus the art teaches a sensor molecules attached to the filter and the capability of binding the target antigen just as

required by the claims. The detection of the particles is an indication of the presence and amount of analyte binding pair members in the biological sample, just as required by the claims (col. 2, lines 47-49). For detecting antigens, an anti-epitope-1 antibody can be on the particle and an anti-epitope-2 antibody can be on the membrane/filter so as to form a sandwich (col. 4, lines 60-65). Thereby teaching an antibody as comprised within a sensor molecule, just as required by the claims. The detection of haptens, antigens, viral agents, tumor antigens, exotoxins, other proteins shed by bacterial or parasitic organisms, antibodies, binding proteins and the like can all be the target molecules (col. 5, lines 1-15).

Example 1 teaches the preparation of the filter, where in the antigen-sensitized filters were placed in holders fitted with syringes (col. 5, lines 42-45). The entire sample mixture was passed through the filter and subjected to detection (col.5, lines 45-54). Table 1 shows that the digoxin filters retained about 80% of the total detected enzyme activity. The example also teaches the detection of the particle can also occur by incubating the filter with the substrate mixture (col.5, lines 59-61). Example 2 teaches detection of the target after passing the sample with a syringe through the filter membrane, thus a pressure controlling apparatus is connected to the filter just as required by the claims. Tables I-IV all show the use of control, positive and negative controls, just as required by the claims. Lentrichia et al., teach attaching labels such as fluorescent molecules and dyes to aid in detection (col. 3, lines 46-49).

Thus, Lentrichia et al., teach a method for assaying a sample for the presence of a target molecule comprising the claimed steps, just as required by the claims.

7. Claims 26-27, 40-43, 45-46 and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Mirkin et al., (US Patent 6,417,340).

The claims are drawn to a method for assaying a sample for the presence of a target molecule comprising: providing said sample suspended in a liquid wherein said sample is suspected of comprising said target molecule; immersing a filter into said liquid containing said sample and pulling said liquid containing said sample transversely through said filter using a pressure-controlling apparatus connected to said filter, wherein said filter comprises a sensor molecule attached thereto and said sensor molecule is capable of specifically binding to said target molecule, if present; binding of said target molecule to said sensor molecule; removing said filter from said sample; detecting the presence of said target molecule specifically bound to said sensor molecule. The dependant claims are drawn to different sensors, control samples, wash steps, secondary sensors and secondary fluorophore labels.

Mirkin et al., teach a system for detecting target nucleic acids using two types of fluorescently-labeled oligonucleotide-nanoparticle conjugates whereby the targets are retained on microporous membrane filter, see Figure 22. Mirkin et al., teach that semiconductor nanoparticles are useful and the art of making semiconductor nanoparticles is well known (col. 16, lines 31-45). Each nanoparticle will have a plurality of oligonucleotides attached to it, thus any complementary sequence can be detected (col. 18, lines 3-7). Detection may be directly n cells, tissue samples, biological fluids such as saliva, urine, blood, serums or other sample types is well known (col. 18, lines 56-60). One method which eases visualization results in using nanoparticle probes

which are hybridized to a target nucleic acid on a glass fiber filter where the liquid is drawn through the filter, followed by subsequent rinsing with water to wash the excess non-hybridized probes through the filter to leave behind an observable spot comprising the retained aggregates (because the aggregates are larger than the pores of the filter) (col. 20, lines 45-60). This technique provides for greater sensitivity since excess nanoparticle probes can be used. Figure 21 shows detecting nucleic acids using nanoparticles having attached oligonucleotides and microspheres having fluorescently labeled oligonucleotides attached thereto wherein the sensor binds the bind. Mirkin et al., also teach the use of different types of oligonucleotide-nanoparticle conjugates, thereby teaching a plurality of different sensor molecules just as required by the claims (col. 28, lines 25-30). Mirkin et al., teach negative and positive controls where a negative results in no detection and a positive result shows changes in color or fluorescence (col. 31, lines 15-25). Example 15 teaches the liquid sample being vacuum-filtered through the membrane filter and the membrane retained the fluorophore-labeled oligonucleotide latex particles. Thus, the art teaches a pressure-controlling device connected to the filter, just as required by the claims. A control experiment using a variety of control samples was also carried out within the example (col. 59, lines 10-15). The example also teaches that background noise was overcome by washing the membrane filter to remove excess probes (col. 59, lines 27-35).

Thus, Mirkin et al., teach a method for assaying a sample for the presence of a target molecule comprising the claimed steps, just as required by the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentrichia et al., (US Patent 4,960,692) in view of Hurley et al., (US Patent 5,256,571).

The claims are drawn to a method for assaying a sample for the presence of a target molecule further comprising a water-soluble alcohol which preserves the sterility of the liquid toward at least one contaminant.

Lentrichia et al., has been discussed above, however Lentrichia et al., do not disclose a sample comprises a water-soluble alcohol in an amount effective to preserve the sterility of the solution toward at least one contaminant.

Hurley et al., teach an alcohol buffer solution for preservation prior to other forms of analysis (col. 2, lines 1-5). Because it is necessary to get a sample at a different time then when analysis is being performed, it is desirable to preserve the cell sample, prevent bacterial growth which may occur because of extended preservation and prevent further interference with the sample (col.1, lines 50-68). The solution also effectively destroys microbial pathogens in a sample and inhibits retroviral activity (col.3, lines 9-11) which preserves the sterility of the sample just as required by the claims. The preferred alcohol is methanol, which is a water-soluble alcohol (col.3, lines 27-30).

In practicing the method, a cell sample is obtained from a patient or other cell source and then the sample is placed in the preservative solution (col. 4, lines 23-33).

Therefore, it would have been prima facie obvious at the time of applicants invention to modify the method for assaying a sample for the presence of a target molecule comprising the claimed steps as taught by Lentrichia et al., to further include using a water-soluble alcohol preserving solution as taught by Hurley et al. No more than routine skill would have been required to incorporate the water-soluble alcohol into the sample, since the prior art teaches the beneficial effects of inhibiting bacterial growth which may affect the sterility of the sample due to preservation. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success, since the prior art teaches that the solution can be used with a wide variety of cell types and allows the cell samples to maintain their integrity and be further analyzed without any interference from the storage and preservation.

Conclusion

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
February 18, 2007

MARK NAVARRO
PRIMARY EXAMINER